



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

5158

February 6, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER

CHI-17-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John V. Ankus, President
Jonal Bakery LTD, d.b.a. Baltic Bakery
4627 S. Hermitage Avenue
Chicago, IL 60609

Dear Mr. Ankus:

An inspection of your firm by the U.S. Food & Drug Administration on December 4, 5 and 12, 2000, documented numerous insanitary conditions. At the conclusion of the inspection, your Manager/Secretary, Mr. Algis J. Ankus, was presented with a Form FDA 483 (Inspectional Observations), listing objectionable conditions observed by the FDA investigator in your plant during the inspection. (A copy of the FDA 483 is enclosed.) A sample of environmental contamination (rat fecal pellets) in your facility was also collected for analysis as part of the inspection.

The insanitary conditions observed during the inspection at your firm cause your products to be adulterated and in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. They are adulterated because they have been prepared, packed and held under conditions whereby they may have been contaminated with rat and insect filth. Specifically, the inspection disclosed the following insanitary conditions:

- Soft, rat fecal pellets were observed in the center and at the east end of the receiving area, where racks of unpackaged product were also stored. Our lab analysis confirmed a sample of rat fecal pellets collected from this area.
- A dead rodent on a glue board was found near the east wall of the receiving area.
- A live fly was noted on a loaf of bread dough just prior to baking.
- Live cockroaches were observed on a pipe in the center of the mixing room.
- A wall hole (which provides a potential access point for rodents) was noted in the mixing room and in the receiving area, near bread processing and/or packaging operations.

- Finished bread products were observed being packaged, stored and shipped in used egg boxes. Egg boxes used for storage and shipping were covered with a grease residue.
- Product residue and/or mold residue and/or rust residue were observed on and/or in the sour-mix blender, the bread sour-mix tote, the water feeder hose for the tote, and the bake-room blender.
- Baked, unpackaged product was noted stored near open doorways and/or under a staircase and ceiling with peeling paint and grease and/or dirt residue.
- Your dough chute was noted uncovered, filled with leftover product, and open to a staircase that contained product residue.
- A stainless steel bucket used in processing was observed to contain multiple cracks, preventing proper cleaning.
- Employees were noted drinking beverages in the mixing and baking area, wearing earrings and hand jewelry during processing, and without beard and total head hair restraint during processing.

Our investigator reported that you have made several corrections in response to our inspection, including removing the rat fecal pellets and the dead rodent, caulking pipe crevices where cockroaches were observed, and coordinating a same-day service visit from your pest control operator. Corrections also included bricking over wall holes, and procedural changes limiting exposure of uncovered product prior to packaging. Our investigator also reported that you have promised to correct other deviations noted during the inspection.

We acknowledge these corrective actions and encourage you to continue such activities as needed to preclude products processed, packaged and stored at your firm from becoming adulterated. Your Manager/Secretary, Mr. Algis J. Ankus, indicated during our inspection that employees last saw a live rat in your facility approximately one-to-two weeks earlier. Your response to insanitary conditions in the current inspection, and your pest control efforts now and in the future, should include a specific, comprehensive plan to monitor and prevent insanitary conditions and practices from escalating to a point where these conditions and your operation are out-of-control.

The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence to each requirement of the federal regulations. We request that you take prompt action to correct all violations.

Please provide this office, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take, or have taken, to correct and prevent the recurrence of these objectionable conditions. Provide the time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to James Karpus, Compliance Officer, at the Chicago District Office.

Sincerely,

\s\
Raymond V. Mlecko
District Director

Enclosure: Form FDA 483

cc with enclosure: Mr. Algis J. Ankus, Manager/Secretary
Jonal Bakery LTD, d.b.a. Baltic Bakery
4627 S. Hermitage Avenue
Chicago, IL 60609